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(11) EP 0715 859 A1

(12)

## EUROPEAN PATENT APPLICATION

(43) Date of publication:

(51) Int Cl.<sup>6</sup>: A61M 1/14

(21) Application number: 95118902.6

(22) Date of filing: 01.12.1995

**(84) Designated Contracting States:**

(30) Priority: 07-12-1994 SE 9404245

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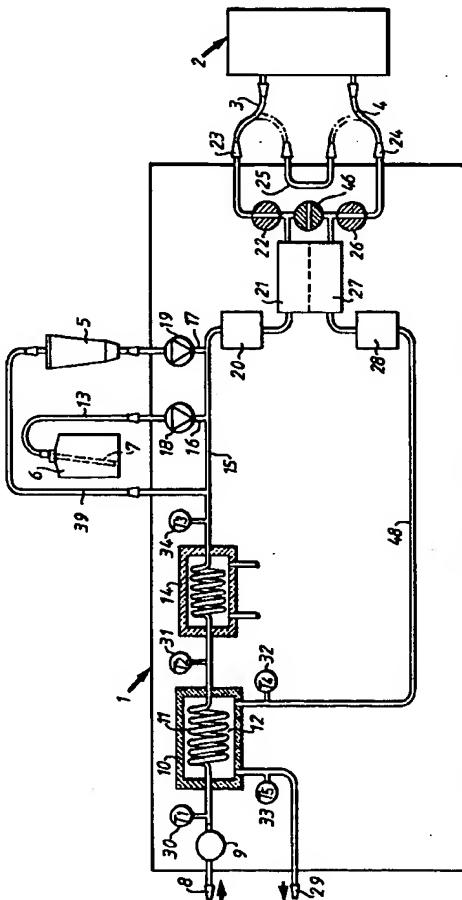
**(54) Method and device for measuring the ultrafiltration volume in a dialysis machine and method for calibrating the device**

(57) Method and device for measuring the flow differential between incoming liquid flow to a dialysis machine and outgoing liquid flow from a dialysis machine, as well as a method for calibration of the device. The dialysis machine comprises a heat exchanger (10) for transfer of heat energy from the outgoing (29) to the incoming (8) liquid flow, a connection (23,24) to a dialyser (2) for feeding the dialysis solution through the dialysate side of the dialyser, a device (20, 28) for attaining an ultrafiltration in the dialyser, and a plurality of temperature sensors (30,31;32,33) for detecting the temperature of the dialysis solution. The flow differential is calculated with help of the equation

$$\Delta Q = Q \times (\Delta T_1 - \Delta T_2) / \Delta T_2$$

where  $\Delta Q$  = the flow differential,  $Q$  = the liquid flow,  $\Delta T_1$  = temperature difference across one side of the heat exchanger and  $\Delta T_2$  = temperature difference across the other side of the heat exchanger. Calibration takes place with built in concentrate pumps (6,16,18).

Fig. 1



**Description****TECHNICAL FIELD**

The invention relates to a method and a device for measuring the difference between incoming liquid flow to a dialysis machine and outgoing liquid flow from a dialysis machine. This flow differential is related to the ultrafiltration volume which arises in a dialyser connected to the dialysis machine.

The invention also relates to a method for calibrating such a device with the help of concentrate pumps which are normally included in a dialysis machine.

**BACKGROUND OF THE INVENTION**

The present invention is intended to be employed in a dialysis machine for measuring and/or monitoring the ultrafiltration during the dialysis procedure. A dialysis machine in which the invention can be employed is disclosed in EP-B1-0278 100 which describes a dialysis machine corresponding essentially to GAMBRO AK 100.

Such a dialysis machine is provided with an inlet for an incoming liquid flow, such as pure water, and one or more inlets for concentrate. The liquids from these inlets are mixed to form a dialysis solution, called dialysate, which is supplied to a dialyser.

The dialyser includes a membrane which divides the dialyser into a blood side and a dialysate side. The dialysis solution passes over the dialysate side and cleans the blood by means of transporting impurities such as urea from the blood through the membrane to the dialysis solution and transporting necessary substances such as bicarbonate from the dialysis solution to the blood. In addition, a quantity of the liquid content in the blood, blood plasma, is drawn from the blood to the dialysis solution, a so-called ultrafiltrate.

The dialysis solution is returned to the dialysis machine and discharged as an outgoing liquid flow from the dialysis machine to a drain.

Furthermore, the dialysis machine comprises a number of various means for regulating the composition of the dialysis solution, for achieving sufficient pressure and flow conditions for the dialysis solution, as well as for regulating and transporting the blood flow on the dialyser's blood side. Thus, the dialysis machine includes a flow measuring device for measuring the dialysis solution flow to and from the dialyser and calculating the ultrafiltrate as a difference between these flows.

DE-A1-41 27 675 discloses a method and device for monitoring the fluid flow in a conduit. A heat impulse is supplied to the fluid and the increase of temperature due to the supplied heat energy is used as a measurement of the mass flow through the conduit. This principle is called a thermal flow meter.

US-A-4 530 759 discloses a method and device for measuring the ultrafiltrate in a dialysis machine using a

balancing device. The balancing device induces an error in the ultrafiltrate measurement due to different temperatures in the two balancing chambers, resulting in a small change of density. This error is compensated for by measuring the temperature difference and applying a correction.

**SUMMARY OF THE INVENTION**

In a medical dialysis apparatus, it is customary to use a second independent measuring devices for safety monitoring of significant properties and operating parameters of the dialysis machine.

The main object of the present invention is to suggest a device which monitors the ultrafiltrate totally independently of the normal operation of the dialysis machine.

According to the present invention, the use of a thermal flowmeter for measuring the ultrafiltration is proposed.

A thermal flowmeter uses the following equation:

$$P = Q \times C \times \Delta T \quad (1)$$

in which  $P$  is the power which is supplied to the liquid and which brings about a change in the temperature of  $\Delta T$  during a mass flow  $Q$  and heat capacity  $C$  of the liquid.

Moreover, it is noted that many dialysis machines today already include, from the beginning or as an option, a heat exchanger which recovers a quantity of the heat content in the outgoing liquid flow from the dialysis machine and transfers this to the incoming liquid flow to the dialysis machine. In this manner, the heating requirement within the dialysis machine is reduced which is an advantage particularly when the power supply from the mains is limited. The heat exchanger can be built into the machine or can be arranged as an accessory outside the machine.

A transfer of heat energy occurs in the heat exchanger from the secondary side to the primary side. The transferred heat energy can be expressed as a loss of heat energy when the liquid passes through the secondary side of the heat exchanger and/or as an addition of heat energy when the liquid passes through the primary side of the heat exchanger. The flow differential between the secondary side and primary side of the heat exchanger can be expressed as a function of the temperature differences across the primary side and the secondary side, as well as the total flow through the heat exchanger.

In a preferred embodiment of the invention, the total flow through the primary side of the heat exchanger is measured with a second thermal flowmeter within the dialysis machine. The dialysis machine comprises a heating device for heating the incoming liquid flow to approximately body temperature, for example 38°C. By measuring the temperature increase across the heating device, as well as the supplied electrical power, the flow

through the heating device can be calculated according to the above equation.

As mentioned above, the dialysis machine comprises inlets for concentrate. These inlets contribute to the flow differential mentioned above. In order to obtain the ultrafiltrate, the incoming concentrate flows must be subtracted from the calculated flow differential. However, the additions of the concentrate flows occur by means of dosage pumps with known and constant displacement, for example ceramic pumps. Accordingly, the concentrate flows are known, for which reason the ultrafiltrate can be calculated. Compensation can also be made for power losses which affect the thermal processes, as well as for changes in the heat capacity and density of the fluids involved.

According to the invention, one of the concentrate pumps can be used to calibrate the ultrafiltration measuring device. Thus, the dialyser is shunted so that no ultrafiltration takes place and the concentrate pumps are set to predetermined "ordinary" values. Then, one of the concentrate pumps is set to an increased flow and the measuring device according to the invention is calibrated in principle to correspond to the increased value of that concentrate pump.

Further properties and features of the invention will be apparent from the annexed claims to which reference is hereby made.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Further objects, advantages and features of the invention will be apparent from the following detailed description of preferred embodiments of the invention, with reference to the attached drawings.

Fig. 1 is a schematic view of a measuring device according to the invention connected to a dialysis machine.

Fig. 2 is a connection diagram which shows how the measuring device can be arranged to achieve reliable measuring values.

Fig. 3 is a cross-sectional view which shows the heat exchanger and the heating device as they can be designed in practise.

#### DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

A dialysis machine is shown in Fig. 1 in which the present invention can be applied.

The dialysis machine 1 comprises an inlet 8 for pure water. Via a valve 9, the inlet 8 leads to the primary side 11 of a heat exchanger 10. The valve 9 can be a shut-off valve and/or a pressure regulating valve.

From the primary side 11, water is fed to a heating device 14 where the incoming water is heated to approximately body temperature, for example about 38°C. The water passes from the heating device 14 through a conduit 15 provided with two inlets 16, 17 for concentrate.

The first inlet 16 is associated with a container 6 which contains A-concentrate (Acid concentrate). The concentrate in the container 6 is drawn up by a pick-up tube 7 and passes via a tube 13 to a concentrate pump 18. The concentrate pump 18 is for example a ceramic type pump and consists of a very accurate dosage pump. The volume of concentrate which is introduced via the inlet 16 is thus determined very accurately by the number of revolutions of the dosage pump 18.

5 A second concentrate, B-concentrate (Bicarbonate concentrate), is introduced via the second inlet 17 by means of a second concentrate pump 19. Water is drawn via a branch conduit from the conduit 15 shortly after the heating device 14 and is introduced in the upper 15 part of a cartridge 15 containing the bicarbonate in powder form. The water passes through the powder and forms a solution of bicarbonate which is substantially saturated. By means of the concentrate pump 19, the desired quantity of B-concentrate is introduced via the inlet 17.

20 The conduit 15 contains various devices which are necessary in a dialysis apparatus, for example conductivity cells for measuring and controlling the dosage pumps 18 and 19. In addition, a degassing device, a pump device, a pH-measurer etc are provided. These devices are symbolized by the box 20 but can be located at different points along the conduit 15. After the device 20, the thus ready prepared dialysate is supplied to a first flow measuring cell 21 and further via a valve 22 to a dialysate outlet 23.

25 A dialyser is shown schematically by reference numeral 2 and is provided with a tube 3 for connection to the dialysate outlet 23, as well as a tube 4 for connection to a dialysate inlet 24. As indicated by dashed lines in Fig. 1, the tubes 3 and 4 can be connected to a shunt conduit 25, for example during the start-up phase of the machine, as well as during disinfection, etc.

30 Dialysis of the blood occurs in the dialyser, which means that ions pass through the membrane of the dialyser from the dialysate to the blood and vice versa. In addition, a fixed quantity of blood plasma is drawn out in the form of an ultrafiltrate.

35 The dialysis solution flows from the dialysate inlet 24 through a valve 26 to a second flow measuring cell 27 and further via a number of devices which are symbolized by the box 28 to the secondary side 12 of the heat exchanger 10 and further to an outlet 29 which is normally connected to a drain. The box 28 contains, for example, a blood leakage detector, a pump device, pressure and temperature measurers, etc, which are positioned at various points along the conduit 48 from the dialysate inlet 24 to the outlet 29.

40 As is apparent from Fig. 1, an inlet 8 for water is provided which, in this description, is termed the incoming flow. In addition, there is an outlet 29 for the consumed dialysate which, in this description, is denoted the outgoing flow. The incoming and outgoing flows lead to and come from the heat exchanger 10.

In the dialysis machine, certain additions occur to the incoming flow. At the inlet 16, concentrate is introduced from an external container 6 which is added to the incoming flow.

At the inlet 17, concentrate is added from a powder cartridge 5. Removal of a flow via a branch conduit from the conduit 15 occurs simultaneously. The net addition via the inlet 17 is thus substantially zero since the same quantity is removed from the conduit 15 via the branch conduit as is added to the conduit 15 via the inlet 17. When the powder dissolves in the cartridge 5, substantially no, or a very small, volume change takes place, though the density and the heat capacity do alter.

An addition of volume to the incoming flow occurs in the dialyser 2 in the form of the ultrafiltrate. It is this ultrafiltrate which is to be monitored according to the present invention. The ultrafiltrate is measured in the dialysis machine as a difference between the flow through the second measuring cell 27 and the flow through the first measuring cell 21.

It will thus be apparent that the difference between the incoming flow through the inlet 8 and the outgoing flow through the outlet 29 consists of the addition of concentrate via the inlet 16 from the container 6, as well as the ultrafiltrate.

In certain machines, the conduit 39 and the cartridge 5 are replaced by a container containing concentrate. In this case, a net addition of a liquid volume to the incoming flow via the inlet 17 will of course occur. Other machines may have only one inlet corresponding to the inlet 16. Machines are also known which use several cartridges 5 with powder concentrate and only small quantities of liquid concentrate.

An increase in the temperature of the incoming flow takes place on the primary side 11 of the heat exchanger 10. This increase in temperature is measured by two temperature sensors 30, 31 which measure the temperature  $T_1$  before the heat exchanger and the temperature  $T_2$  after the heat exchanger, respectively. On the secondary side of the heat exchanger there are two temperature sensors 32, 33 which measure the incoming temperature  $T_4$  to the secondary side of the heat exchanger and the outgoing temperature  $T_5$ . In addition, a further temperature sensor 34 is positioned after the heating device 14 to measure the outgoing temperature  $T_3$  from the heating device.

With the help of the temperature sensors 34 and 31 as well as by measuring the energy addition to the heating device 14, the total incoming flow can be calculated. The calculation occurs with the above equation (1). In order to obtain an accurate value of the flow, it may be necessary that the heating device 14 be heat insulated relative to the surroundings so that the supplied electrical power really is transferred to the liquid. Alternatively, or in addition, the supplied power can be compensated for by possible emissions to the surroundings.

Transfer of heat energy takes place in the heat exchanger from the secondary side of the heat exchanger

to its primary side. If the heat exchanger is well insulated, these quantities of heat energy are equally large. If the primary side is denoted by suffix 1 and the secondary side denoted by suffix 2, the following equation is obtained according to the above equation (1):

$$Q_1 \times C_1 \times \Delta T_1 = Q_2 \times C_2 \times \Delta T_2 \quad (2)$$

If it is assumed that  $C_1 = C_2$  and  $Q_2 = Q_1 + \Delta Q_1$ , the following equation is obtained:

$$\Delta Q_1 / Q_1 = (\Delta T_1 - \Delta T_2) / \Delta T_2 \quad (3)$$

$\Delta Q_1$  thus corresponds to the additions which takes place within the dialysis machine between the primary side of the heat exchanger and its secondary side. These additions occur in Fig. 1 via the inlet 16,  $Q_A$ , as well as the ultrafiltration,  $Q_U$ , via the dialyser 2. The quantity which passes via the inlet 16 is known since the dosage pump 18 is very accurate. Thus, the quantity of ultrafiltration can be determined.

In equation (3), it is assumed that the heat capacity for the incoming flow, normally pure water, via the inlet 8 is the same as the heat capacity for the outgoing flow via the outlet 29. This is not totally correct since salts have been added via the inlets 16 and 17, which change the density of the liquid as well as to a certain extent its specific heat capacity. The additional flow via the dialyser 2 also changes these conditions somewhat.

An analysis of equation (2) shows, however, that a small constant change of the heat capacity only gives a substantially constant addition to the calculated flow differential  $\Delta Q_1$  calculated according to equation (3) with a correction factor  $\Delta Q_c$  according to equation (4):

$$\Delta Q_c / Q_1 = (1 - C_1 / C_2) \times \Delta T_1 / \Delta T_2 \quad (4)$$

If  $\Delta T_1 / \Delta T_2$  is constant, which is the case during measurement of a small flow differential  $\Delta Q_1$ , the addition will be approximately constant.

The same applies if it is assumed that a fixed portion of the heat energy on the secondary side is emitted to the surroundings. The correction factor  $\Delta Q_p$  is thus determined by the following equation (5):

$$\Delta Q_p / Q_1 = (1 - P_2 / P_1) \times \Delta T_1 / \Delta T_2 \quad (5)$$

Accordingly, the ultrafiltration  $\Delta Q_U$  is obtained according to the following equation (6):

$$\Delta Q_U = \Delta Q_1 - \Delta Q_A - \Delta Q_c - \Delta Q_p \quad (6)$$

The size of the correction factors can be measured during start up of the dialysis machine with those parameters which are necessary for the dialysis treatment in question.

It is to be noted that the heat capacity for the ingoing and outgoing liquid flow is also dependent on its oxygen content and the content of other gases, whereby account can also be taken of these factors.

It is apparent from the above equations that the calculation is based on measurement of the differences be-

tween two or four temperatures. It is desirable to perform necessary calculations in a computer. If the measured temperatures are digitalized and the calculation of the difference is made in the computer, digitalization errors easily affect the result. In such case, A/D converters with very high resolution must be used which in principle integrate the measured temperature value over a relative long period.

Since it is  $\Delta T_1 - \Delta T_2$  and  $\Delta T_2$  which are of interest, according to a preferred embodiment of the invention it is proposed to connect the temperature sensors according to Fig. 2. The temperature sensors which are employed consist of heat sensitive resistors, thermistors, in which the resistance is substantially proportional to the temperature. If these thermistors are connected in series in the manner as indicated in Fig. 2,  $\Delta T_2$  and  $\Delta T_1 - \Delta T_2$  respectively can be measured via adjustment of the switch 35. The thermistors  $T_2$ ,  $T_4$ ,  $T_3$  and  $T_1$  are connected in series and a common constant current  $I_{\text{const}}$  passes through the thermistors. The current is generated by a constant current generator (not shown).

The mid-point between the thermistors  $T_5$  and  $T_4$  is connected to the positive input of an OP amplifier 36. The voltage which arises before the thermistor  $T_1$  and after the thermistor  $T_2$  respectively is fed via the switch 35 to the negative input of the OP amplifier 36. Thus, a voltage is obtained from the output of the OP amplifier 36 which corresponds to  $(-T_1 - T_5 + T_4 + T_2) = \Delta T_1 - \Delta T_2$ . By switching the switch 35 to the second position, the voltage from the thermistor  $T_5$  and thermistor  $T_4$  respectively is fed to the OP amplifier 36 and the output thereof provides a voltage corresponding to  $(-T_1 + T_4) = -\Delta T_2$ . The two attained voltages are fed to an AD converter 37 and further to a calculating computer 47.

In the position shown in Fig. 2,  $\Delta T_1 - \Delta T_2$  is measured which has a very much lower value than  $\Delta T_2$  which is measured in the second position of the switch 35. The switch 35 can be complimented by a further section which alters the value of the resistance 38 which determines the amplification of the OP amplifier 36 so that the amplification increases by a suitable factor, for example by a factor 10. In this manner an AD converter 37 with lower resolution can be used.

By providing the computer 47 with measurement values of  $\Delta T_2$  and the difference  $\Delta T_1 - \Delta T_2$ , the computer can calculate  $\Delta T_1$  and thus also the ratio  $\Delta T_1/\Delta T_2$ . This can be used to calculate  $\Delta Q_C$  and/or  $\Delta Q_p$  according to equation (4) and (5). This is assuming that the ratio  $C_1/C_2$  and/or  $P_1/P_2$  is known. The ratio  $C_1/C_2$  is a function of the temperature of the incoming and outgoing liquid, their salt concentration and densities, dissolved or dispersed gases in the liquids, as well as other factors. The calculating computer 47 can calculate this ratio, though sometimes needs further information such as the temperature of the incoming water  $T_1$  or  $T_2$ .

If  $T_2$  is measured, this can also be used to calculate  $Q_1$ , i.e. the incoming flow, by means of using the above equation (1) and the heating device 14.  $T_3$  is regulated

by the dialysis machine to a predetermined temperature, for example 38°C. Thus, if  $T_2$  is known, then so too is the difference  $T_3 - T_2$  across the heating device. By measuring the addition of power to this device, i.e. the current and voltage, the flow  $Q_1$  can be calculated.

Since temperature differences are of interest, it can be practical to employ a thermal element, a so-called thermocouple, where a voltage is attained across the thermocouple which is proportional to the temperature difference between two points or joints. The thermal element uses the property that a potential difference arises at the junction between two conductors of different material, for example copper and iron. The potential difference is temperature-dependent. By using two junction locations which have different temperatures, a voltage arises across the thermocouple. In this manner, the voltage which arises can be digitalized and forms a measurement of  $\Delta T_1$  and  $\Delta T_2$  respectively.

According to the invention, other methods can also be used for measuring the total incoming flow  $Q_1$ , for example by measuring the pressure difference across a throttling device or using some other flow meter. It is also possible to use an estimated or nominal value, for example a value inputted by the user.

A cross-section of a heat exchanger 10 and a heating device 14 is shown in Fig. 3 which may be used according to the present invention. The heat exchanger 10 consists of an outer sleeve 40 in the form of a tube. The inner surface of the tube is provided with a spiral-shaped groove 41 which runs from an inlet 42 to an outlet 43. The inlet 42 and the outlet 43 are provided with temperature sensors 32, 33. The spiral shaped groove 41 is delimited inwardly by a metal cylinder 45. The thus described components together form the secondary side of the heat exchanger.

Within the metal cylinder 45, an inner cylinder 44 is located which is provided with threads 48. The threads 48 seal against the metal cylinder 45 and form a screw-shaped groove 49 which forms the primary side of the heat exchanger. An inlet 50 is provided with a temperature sensor 30 and an outlet 51 is provided with the temperature sensor 31.

The heating device 14 consists of the same outer sleeve 40 as the heat exchanger, though the metal cylinder 45 is replaced by a heating cartridge 52. The heating device 14 is located close to the heat exchanger 10 so that the temperature sensor 31 can be regarded as measuring the input temperature to the heating device 14. The heating device thus has an inlet 53 and an outlet 54, whereby the outlet is provided with the temperature sensor 34.

The temperature sensors are of the type Pt 100 (thermistor) and consist principally of a thin metal tube containing a heat sensitive resistor, as well as a connection head through which connection conduits pass.

In order to obtain an estimation as to how large the power losses to the surroundings are, a temperature sensor (not shown) can be used which measures the

surrounding temperature within the dialysis machine and/or outside thereof. With the help thereof, the calculating computer can estimate the power losses in the heat exchanger 10, the heating device 14 and the dialysis machine in general.

It may also be possible to reduce the power loss to the surroundings by heating the heat exchanger's surroundings to a temperature approaching the average value of  $T_4$  and  $T_5$ . Thus, the heat exchanger 10 can possibly attain a heat energy surplus from the surroundings. In certain applications, it is suitable to insulate the heat exchanger 10 and/or the heating device 14 by surrounding them with heat-insulating material of suitable thickness.

In order to obtain necessary accuracy of the measurement of the flow differential via the heat exchanger and according to the invention, it is necessary that sufficient temperature differences are attained across the heat exchanger, for example at least 5°C between the inlet and the outlet on the primary side. This is normally not difficult to obtain since the temperature of the incoming flow is normally less than around 20°C. In warmer countries where the temperature can approach 30°C, it can be problematic to achieve sufficient accuracy in measuring the flow differential. The calculating computer 47 can thus be arranged to warn the user that the measurement of the ultrafiltrate is taking place with reduced accuracy.

To obtain a practically useful measuring device for the flow differential of the ultrafiltrate, it can be suitable to calibrate the measuring device every time it is used. This is possible to effect with the components which are normally present in the dialysis machine, in the dialysis machine according to Fig. 1 with the help of the dosage pump 18.

During the start of a dialysis machine, the dialyser 2 is "primed" by allowing normal dialysis solution to pass on the dialysis side of the dialyser 2, whilst sterile salt solution passes on the blood side. In doing so, the dialysis machine is operated so that it produces dialysis solution with normal concentration via the dosage pumps 18 and 19.

According to the present invention, calibration is attained in the following manner. The dialysis machine is started in a normal manner and the dialyser is "primed" whereby the dialysis machine attains normal operating temperatures. Thereafter the valves 22 and 26 are switched so that the dialyser 2 is disconnected and a shunt valve 46 is connected in and shunts the dialysate flow from the measuring cell 21 to the measuring cell 27. This connection is used to calibrate the measuring cells 21 and 27 to the same flow.

By measuring the temperature differences in the heat exchanger 10 in this position, a fixed flow differential is obtained with regard to the inflow via the inlet 16,  $\Delta Q_A$ , the difference in the heat capacity between the incoming flow and the outgoing flow  $\Delta Q_C$  as well as power losses in the heat exchanger  $\Delta Q_p$  since the ultrafiltration

in this connection is zero. The three correction factors in the equation (6) can thus be determined.

Thereafter the speed of the dosage pump 18 is increased by a predetermined value, for example an increase of 10 ml/min. from, for example, about 15 ml/min. to about 25 ml/min. This provides a simulation of an ultrafiltration of 10 ml/min. and the new value of  $\Delta Q_1$  in the heat exchanger is read off by the calculating computer. In this manner, a calibration factor is attained which can be used for calculating the ultrafiltration in the subsequent measurements.

By the addition of an extra quantity of concentrate via the inlet 16, an increase in the heat capacity  $C_2$  and density of the outgoing flow is obtained. This change is however small and can be ignored or compensated for by the calculating computer.

The correction factor which arises during this calibration can depend on possible original measuring errors in the measuring value of the total incoming flow  $Q_1$  or diverse losses of other types. The calibration can also be used to obtain a nominal value of the incoming flow  $Q_1$  which is later used in subsequent calculations, i.e. measuring of  $Q_1$  is not required.

In the above, measurement of the incoming flow  $Q_1$  has been given which is normally preferred when the conditions are favourable for measurement of precisely that incoming flow. Nothing prevents the outgoing flow  $Q_2$  to be measured, (or estimated) if it should be preferred in a particular case. The different equations will in principle be the same as those given above but with altered suffixes. The use of the outgoing flow  $Q_2$  as a basis for the calculations is obviously equivalent.

The invention has been described above with the aid of preferred embodiments described with reference to the drawings. The various properties and features can be combined in other ways than those given in the drawings, which will be obvious to the skilled person. Such modifications and changes are intended to be embraced by the scope of the invention as defined by the appended claims.

## Claims

45 1. Method for measuring the flow differential between incoming liquid flow to a dialysis machine and outgoing liquid flow from a dialysis machine, whereby the dialysis machine comprises:

a heat exchanger for transfer of heat energy from the outgoing to the incoming liquid flow, a connection to a dialyser for feeding of dialysis solution through the dialysate side of the dialyser, a device for achieving an ultrafiltration in the dialyser, a plurality of temperature sensors for detecting the temperature of the dialysis solution,

characterized by measuring the temperature differences across the primary side of the heat exchanger and the secondary side of the heat exchanger respectively, and calculating the flow differential between the incoming and the outgoing liquid flows with help of said temperature differences.

2. Method according to claim 1, characterized by obtaining the total incoming or outgoing liquid flow, for example with a thermal flow meter, and calculating the flow differential with help of the equation:

$$\Delta Q = Q \times (\Delta T_1 - \Delta T_2) / \Delta T_2$$

where

$\Delta Q$  = the flow differential

$Q$  = the liquid flow

$\Delta T_1$  = temperature difference across one side of the heat exchanger

$\Delta T_2$  = temperature difference across the other side of the heat exchanger

3. Method according to claim 1 or 2, in which the dialysis machine is provided with an inlet for concentrate, characterized in that the calculated differential flow is compensated for by differences in the heat capacity between the incoming and outgoing liquid flows.

4. Method according to any one of the previous claims, characterized in that the calculated flow differential is compensated for by heat energy losses in the heat exchanger and/or the dialysis machine.

5. Method according to any one of claims 2-4, characterized in that the total incoming or outgoing liquid flow is obtained by using a nominal value of said flow, for example a value of desired flow inputted by the user.

6. Method according to any one of claims 2-4, characterized in that the total incoming or outgoing liquid flow is obtained by measuring the temperature difference across a heating device and measuring supplied power to the heating device, possibly compensated for losses to the surroundings, and calculating the liquid flow with help of the equation:

$$Q = k \times P / \Delta T$$

where

$Q$  = the liquid flow

$k$  = a constant

$P$  = supplied power (possibly compensated)

$\Delta T$  = temperature difference

7. Device for measuring the flow differential between

incoming liquid flow to a dialysis machine and outgoing liquid flow from a dialysis machine, whereby the dialysis machine comprises:

a heat exchanger (10) for transfer of heat energy from the outgoing (29) to the incoming (8) liquid flow,

a connection (23,24) to a dialyser (2) for feeding of dialysis solution through the dialysate side of the dialyser,

a device (20,28) for achieving an ultrafiltration in the dialyser,

a plurality of temperature sensors for detection of the temperature of the dialysis solution,

characterized by temperature sensors (30,31; 32,33) for measuring the temperature differences across the primary side and secondary side respectively of the heat exchanger, and a first calculating means (47) for calculating the flow differential between the incoming and outgoing liquid flows with help of said temperature differences.

8. Device according to claim 7, characterized by a second calculating means (14,34,31) for calculating the total incoming or outgoing liquid flow, for example with a thermal flowmeter, whereby the flow differential is calculated by the first calculating means with help of the equation:

$$\Delta Q = Q \times (\Delta T_1 - \Delta T_2) / \Delta T_2$$

where

$\Delta Q$  = the flow differential

$Q$  = the liquid flow

$\Delta T_1$  = temperature difference across one side of the heat exchanger

$\Delta T_2$  = temperature difference across the other side of the heat exchanger

9. Device according to claim 7 or 8 in which the dialysis machine is provided with an inlet (16) for concentrate, characterized by a first compensation means (37, 47, equation 4) for compensation of the calculated flow differential for differences in the heat capacity between incoming and outgoing liquid flows.

10. Device according to any one of claims 7-9, characterized by second compensation of means (37, 47, equation 5) for compensating for the calculated flow differential for heat energy losses in the heat exchanger (10) and the dialysis machine (1).

11. Device according to any one of claims 8-10, characterized in that the second calculating means for calculating the total incoming or outgoing liquid flow uses a nominal value of said liquid flow, for example a value of the desired flow inputted by the user.

12. Device according to any one of claims 8-10, characterized in that the second calculating means for calculating the total incoming or outgoing liquid flow is arranged to measure the temperature difference across a heating device (14) and measures supplied power to the heating device, possibly compensated for losses to the environment, and in that the liquid flow is calculated with help of the equation:

$$Q = k \times P / \Delta T$$

10

where

Q = the liquid flow  
 k = a constant  
 P = supplied power (possibly compensated) 15  
 $\Delta T$  = temperature difference

13. Device according to any one of claims 7-12, characterized in that the heat exchanger (10) and the heating device (14) are provided with an insulating jacket. 20

14. Method for calibrating of a device according to any one of claims 7-13 for measuring the flow differential between incoming liquid flow to a dialysis machine and outgoing liquid flow from a dialysis machine, whereby the dialysis machine comprises:

a heat exchanger (10) for transfer of heat energy from the outgoing (22) to the incoming (8) liquid flow, 30  
 an inlet (16) for a concentrate solution (6),  
 a connection (23,24) to a dialyser (2) for measuring the dialysis solution through the dialysate side of the dialyser, 35  
 a device (20,28) for attaining an ultrafiltration in the dialyser,  
 a plurality of temperature sensors for measuring temperature differences, characterized by disconnecting the ultrafiltration in the dialyser by means of a shunt arrangement (22,24,46) 40  
 during normal operation of the dialysis machine with a view to preparation and administration of the dialysis solution;  
 altering the quantity of supplied concentrate solution (6) via said inlet (16) and calibrating the device for measuring the flow differential by means of said alteration which simulates a known ultrafiltration. 45

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Fig.1

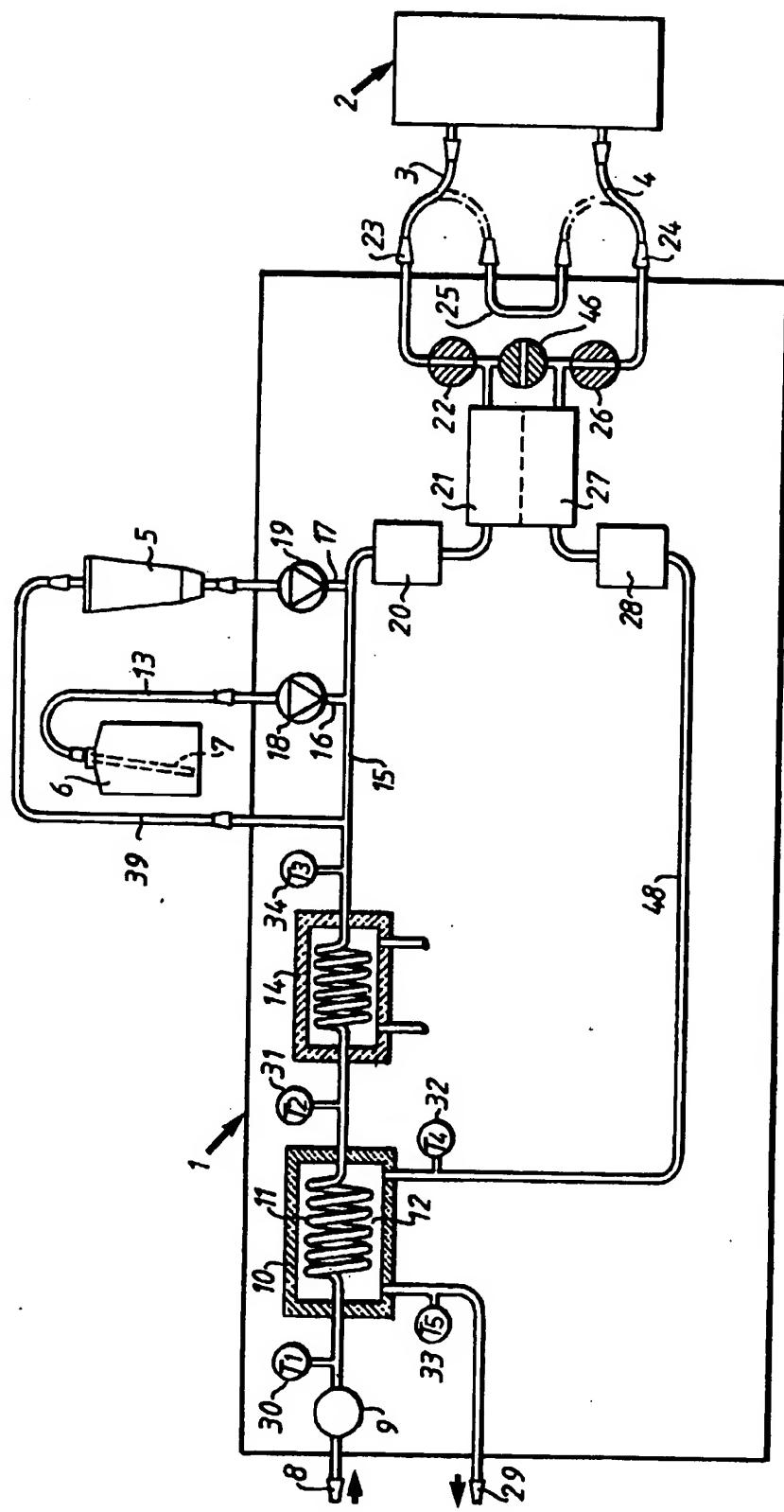


Fig. 2

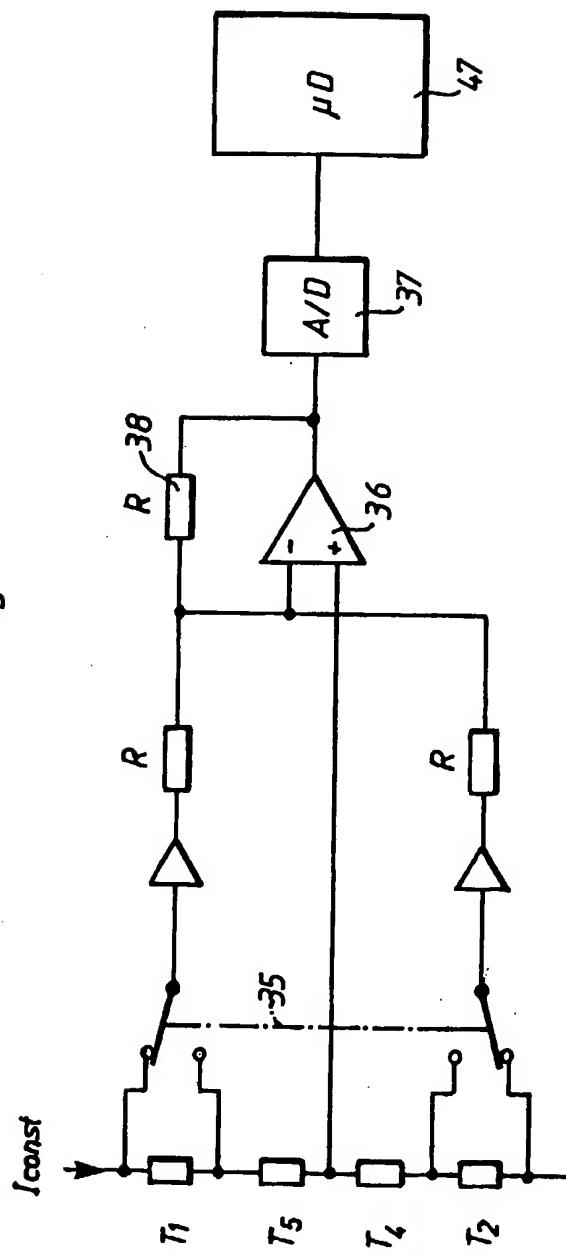
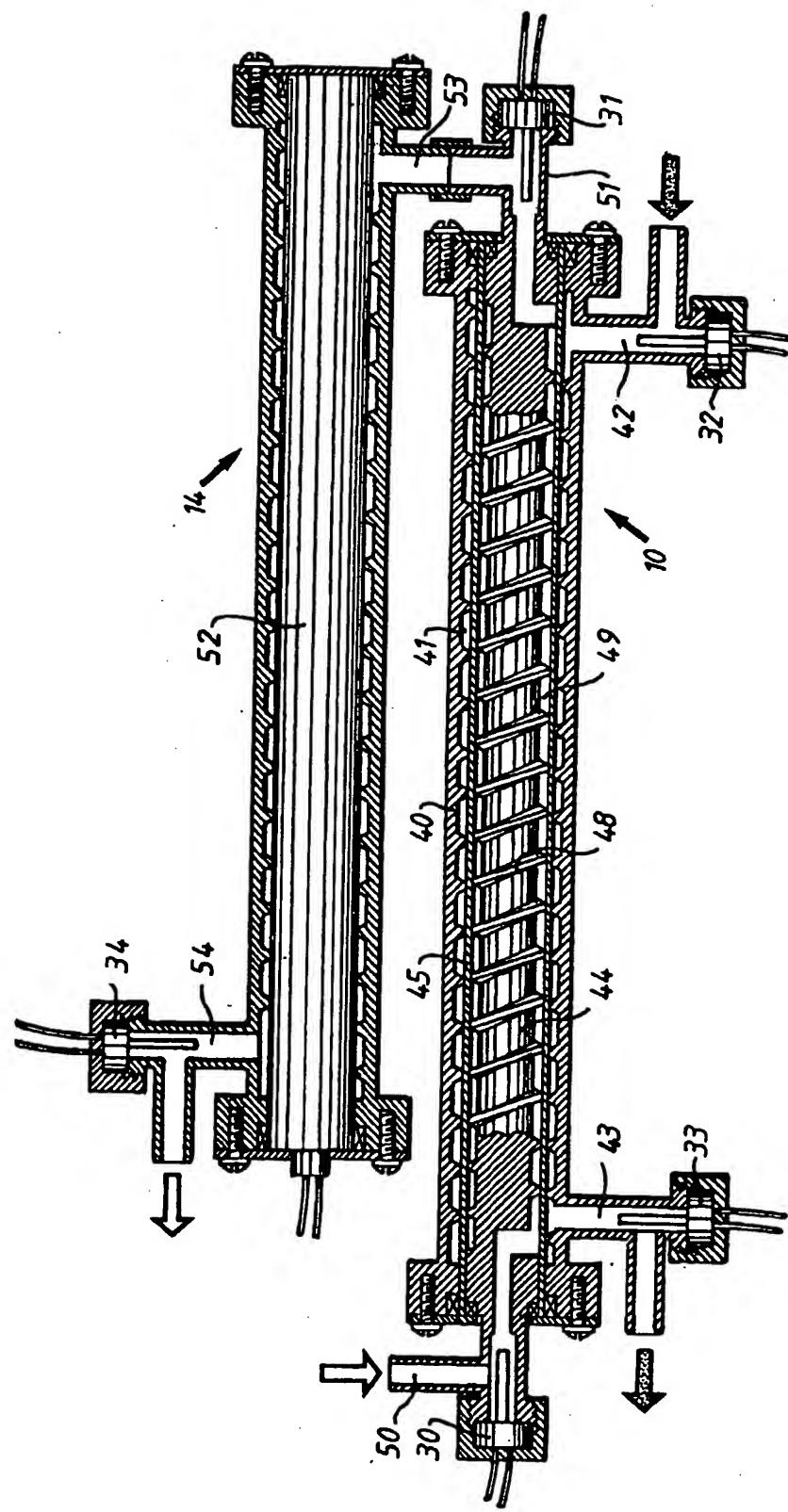


Fig. 3





European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 95 11 8902.6

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
X	US, A, 4530759 (WILFRIED SCHÄL), 23 July 1985 (23.07.85) * column 6, line 39 - column 7, line 45; column 12, line 1 - line 52; column 13, line 4 - line 32, abstract *	1-14	A61M 1/14
A	DD, A1, 235720 (VEB MESSGERÄTEWERK ZWÖNITZ), 14 May 1986 (14.05.86)	1-14	
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TECHNICAL FIELDS SEARCHED (Int. Cl.6)			
A61M			
The present search report has been drawn up for all claims			
Place of search	Date of completion of the search	Examiner	
STOCKHOLM	28 March 1996	INGER LÖFGREN	
<b>CATEGORY OF CITED DOCUMENTS</b> X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			